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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,970	07/19/2002	Tai-Tung Yip	16866-38-IPC	6649
7590	11/17/2004			
Peter K Seperack Townsend and Townsend and Crew Two Embarcadero Center 8th Floor San Francisco, CA 94111			EXAMINER FETTEROLF, BRANDON J	
			ART UNIT 1642	PAPER NUMBER

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/088,970	<b>Applicant(s)</b> YIP ET AL.	
	<b>Examiner</b> Brandon J Fetterolf, PhD	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-83 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input checked="" type="checkbox"/> Other: <u>Molecular Weight Determination.</u>    |

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Yip *et al.*

Claims Pending: 1-83

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-17, and 19-23, as specifically drawn to the special technical feature of a method for adding a prostate cancer diagnosis.

Group 2, claim(s) 13 and 18, as specifically drawn to the special technical feature of a method of aiding a prostate cancer diagnosis by determining the test amounts of a plurality of markers.

Group 3, claim(s) 24-48 and 50-59, as specifically drawn to the special technical feature of a method of detecting a marker, wherein the marker is differentially present in samples of a prostate cancer patient and a benign prostate hyperplasia patient.

Group 4, claim(s) 24, 47, 49-50, 58, and 60, as specifically drawn to the special technical feature of a method of detecting a plurality of marker, wherein the markers are differentially present in samples of a prostate cancer patient and a benign prostate hyperplasia patient.

Group 5, claim(s) 61-83, as specifically drawn to the special technical feature of a kit for aiding a diagnosis of prostate cancer.

The inventions listed as Groups 1-5 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups 1-5 appears to be a method of diagnosing prostate cancer by determining the amount of a polypeptide having an apparent which is differentially resented in samples of a prostate cancer patient and a benign prostate hyperplasia patient, wherein the polypeptide has an apparent molecular weight of less than 27,000 Da.

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However, Zetter *et al.* (US 5,858,681, 1999) teach an amino acid sequence set forth in SEQ ID NO: 2 referred to as “thymosin B15” and a method for diagnosing cancer, especially prostate, lung, melanoma, and breast cancer in a patient by measuring levels of thymosin B15 in a biological specimen obtained from a patient (column 2, lines 60-64). Specially, the patent discloses (Table 1) that thymosin B15 (SEQ IN NO: 2) is differentially present in prostate carcinoma compared to benign prostate hyperplasia. Zetter *et al.* further disclose the amino acid sequence set forth in SEQ ID NO: 2 as consisting of 45 amino acids which appears to have a molecular weight that is less than 27,000 Da, i.e. 5304.10 Da (see attached from [www.Scripps.edu/~cdputnam/protcalc.html](http://www.Scripps.edu/~cdputnam/protcalc.html)).

Therefore, the technical feature linking the inventions of Groups 1-5 does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

### *Species Election*

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Claims 2, 5, 39, 43, 51, and 55, contain a polypeptide having an apparent molecular weight of:

- 1) 2276 Da
- 2) 2530 Da
- 3) 2095 Da
- 4) 3030 Da
- 5) 3038 Da
- 6) 3038 Da
- 7) 3224 Da
- 8) 3600 Da
- 9) 3835 Da
- 10) 3915 Da
- 11) 3933 Da
- 12) 4175 Da

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13) 4423 Da

14) 4480 Da

ect.

Claims 25-33, contain one of the following “absorbents”:

- 1) Hydrophobic group and an anionic group
- 2) Polystyrene bead functionalized with a sulfonate group
- 3) Hydrophobic Group
- 4) Aliphatic C<sub>16</sub> hydrocarbon group
- 5) Metal Chelating group with/without Metal ion
- 6) Antibody

Claims 65-73 contain one of the following “substances”:

- 1) Hydrophobic group and an anionic group
- 2) Polystyrene bead functionalized with a sulfonate group
- 3) Hydrophobic Group
- 4) Aliphatic C<sub>16</sub> hydrocarbon group
- 5) Metal Chelating group with/without Metal ion
- 6) Antibody

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The products of the above species represent separate and distinct molecules with different structures and functions such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Additionally, the steps and reagents of the above species are completely distinct and impart different biological functions and uses such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

**Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD  
Examiner  
Art Unit 1642

BF

  
**GARY NICKOL**  
**PRIMARY EXAMINER**